PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B1075.71014	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/09618	International filing date *(day/month/year)* 29 March 2004 (29.03.2004)	Priority date *(day/month/year)* 28 March 2003 (28.03.2003)
International Patent Classification (IPC) or national classification and IPC IPC: **A61B 18/18**(2006.01) USPC: 606/41		
Applicant C.R. BARD, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07 April 2005 (07.04.2005)	19 June 2007 (19.06.2007)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda Dvorak Telephone No. (703) 308-0858

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:
pages 1-13 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 14-19 received by this Authority on 07 April 2005 (07.04.2005)
pages* NONE received by this Authority on

☒ the drawings:
pages 1-6 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 8-10,14,15 and 20-31

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 8-10,14,15 and 20-31

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest, and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-7, 11-13, 16-19, 32 and 33, drawn to an axially adjustable electrode.

Group II, claim(s) 8-10, 14, 15 and 20-31, drawn to a radially adjustable electrode.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical features for each invention are distinctly different and solve different problems such as the adjustment of the length of a lesion (Group I) and treating vessels with different diameters (Group II).

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-7, 11-13, 16-19, 32 and 33

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 2-7, 16-19 and 32	YES
	Claims 1, 11-13 and 33	NO
Inventive Step (IS)	Claims 2-7, 16-19 and 32	YES
	Claims 1, 11-13 and 33	NO
Industrial Applicability (IA)	Claims 1-7, 11-13, 16-19, 32 and 33	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1, 11-13 and 33 lack novelty under PCT Article 33(2) as being anticipated by FLEISCHMAN et al (6,514,246). Applicant's amendments are not deemed to obviate this rejection, or those that follow. In particular, applicant contends that the prior art references all require a movable sheath to adjust the length of the electrode. The examiner agrees with this characterization, but points out that the claims as amended do not preclude such a device from reading on the rejected claim language. The same arguments are applicable for the following two prior art rejections as well.

Claims 1, 11-13 and 33 lack novelty under PCT Article 33(2) as being anticipated by FRANCISCHELLI et al (6,488,680).

Claims 1, 11-13 and 33 lack novelty under PCT Article 33(2) as being anticipated by VALLEYLAB INC. (WO 95/20360).

Claims 2-7, 16-19 and 32 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an electrode having two movable parts inside and outside each other as recited in these claims.

Claims 1-7, 11-13, 16-19, 32 and 33 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------

CLAIMS

1. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode disposed on the shaft wherein the electrode is convertible from a first configuration in which the electrode has a first axial size and a first radial size to a second configuration in which the electrode has a second axial size and maintains the first radial size.

2. The catheter according to claim 1, wherein the ablation electrode comprises a first electrode portion and a second electrode portion, the second electrode portion having a length and being moveable in the axial direction of the catheter, wherein in the first configuration more of the second electrode portion length is contained within the first electrode portion than in the second configuration.

3. The catheter according to claim 2, wherein in the first configuration, the second electrode portion length is fully contained within the first electrode portion.

4. The catheter according to claim 2, wherein the ablation electrode comprises a third electrode portion that is at least partially contained within the second electrode portion in the first configuration.

5. The catheter according to claim 2, wherein a pull wire is connected to the second electrode portion.

6. The catheter according to claim 1, wherein the ablation electrode is a ring electrode.

7. The catheter according to claim 6, wherein the first electrode portion and the second electrode portion are cylindrical.

8. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode disposed on the shaft and having an outer surface, wherein the electrode is convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in which the electrode outer surface has a second radial size and maintains the first axial size.

9. The catheter according to claim 8, further comprising an inner shaft portion and an outer shaft portion, the outer shaft portion having a longitudinal slot, wherein

the ablation electrode comprises a flexible, electrically-conductive plate having a first end and a second end; and

the first end is attached to the outer shaft portion, the plate passes through the longitudinal slot, and the second end is attached to the inner shaft portion.

10. The catheter according to claim 9, wherein rotation of the inner shaft portion relative to the outer shaft portion converts the electrode from the first configuration to the second configuration.

11. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode comprising a metal element disposed on the shaft which, when exposed, forms a longitudinally continuous outer ablating surface area, wherein the longitudinal extent of the metal element on the shaft is adjustable.

12. The catheter according to claim 11, wherein the electrode is substantially comprised of at least one of: platinum; silver; gold; chromium; aluminum and tungsten.

13. The catheter according to claim 11, wherein the electrode is substantially comprised of a combination of at least two of: platinum; silver; gold; chromium; aluminum and tungsten.

14. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode comprising a metal sheet disposed on the shaft, the metal sheet forming an electrode outer surface that is substantially continuous along both a longitudinal direction and a circumferential direction; wherein

the electrode is convertible from a first configuration in which the electrode outer surface has a first radial size to a second configuration in which the electrode outer surface has a second radial size.

15. The catheter according to claim 14, wherein the ablation electrode is cylindrical.

16. An ablation electrode for ablating tissue, comprising:

a first ablation electrode portion configured for mounting on a catheter shaft, the first ablation electrode portion having an outer surface configured to emit electrical energy; and

a second ablation electrode portion configured for mounting on the catheter shaft, the second ablation electrode portion having a surface configured to emit electrical energy; wherein

the second ablation electrode portion is moveable from a first position substantially inside the first ablation electrode portion to a second position substantially outside the first ablation electrode portion.

17. The ablation electrode according to claim 16, further comprising a third ablation electrode portion configured for mounting on the catheter shaft, the third ablation electrode portion having a surface configured to emit electrical energy, wherein

the third ablation electrode portion is moveable from a first position substantially inside the second ablation electrode portion to a second position substantially outside the second ablation electrode portion.

18. The ablation electrode according to claim 16, in combination with a longitudinal catheter shaft for positioning an ablation electrode within a patient's body,

wherein the first ablation electrode and the second ablation electrode are mounted on the catheter shaft.

19. The combination according to claim 18, further comprising a pull wire configured to move the second electrode portion.

20. A catheter shaft comprising:

an outer shaft portion having a longitudinal passage extending through an outer surface;

an inner shaft portion;

an electrode surface with a first end and a second end, the first end coupled to the inner shaft portion, and the second end coupled to the outer shaft portion, wherein the electrode surface passes through the longitudinal passage;

one of the outer shaft portion and the inner shaft portion is rotatable relative to the other of the outer shaft portion and the inner shaft portion; and

relative rotation of the inner shaft portion and the outer shaft portion extends the electrode surface in a radial direction away from the outer shaft portion.

21. The catheter shaft according to claim 20, wherein relative rotation of the inner shaft portion and the outer shaft portion retracts the electrode surface in a radial direction toward the outer shaft portion.

22. The catheter shaft according to claim 20, wherein the inner shaft portion and the outer shaft portion are cylindrical.

23. The catheter shaft according to claim 20, wherein the electrode surface comprises at least one of: platinum; silver; gold; chromium; aluminum and tungsten.

24. A catheter shaft comprising:

an outer shaft portion having a passage extending through an outer surface;

an inner shaft portion;

an ablation electrode member configured to pass through the passage; and

a biasing element that biases the electrode member.

25. The catheter shaft according to claim 24, wherein the inner shaft portion is configured to urge the ablation electrode member through the passage in a direction away from the inner shaft portion when the inner shaft portion rotates.

26. The catheter shaft according to claim 25, wherein the biasing element is configured to bias the electrode member toward the inner shaft member.

27. The catheter shaft according to claim 26, wherein the passage is a longitudinal slot.

28. the catheter shaft according to claim 27, wherein the ablation electrode member is a fin.

29. The catheter shaft according to claim 27, comprising two ablation electrode members.

30. The catheter shaft according to claim 27, wherein the two ablation electrode members extend in opposite directions to one another.

31. The catheter according to claim 24, wherein the ablation electrode member is comprised substantially of metal.

32. A catheter according to claim 16, wherein the first ablation electrode portion and the second ablation electrode portion are electrically connected.

33. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an electrically conductive element disposed on the shaft and connectable to an energy supply, an exposed portion of the electrically conductive element being usable as an ablation electrode, wherein the electrically conductive element is convertible from a first configuration, in which the electrically conductive element has a first axial length and

a first radial size along a first axial section of the shaft, to a second configuration in which the electrically conductive element has a second, longer axial length and maintains the first radial size along the first axial section of the shaft.